

Laboratories: CMS Flexibilities to Fight COVID-19

The Trump Administration is issuing an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. Made possible by President Trump's recent emergency declaration and emergency rule making, these temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) to ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 2) remove barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states so the healthcare system can rapidly expand its workforce; 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

COVID-19 Diagnostic Testing

- Medicare will pay when laboratories can send trained technicians to a beneficiary's home, including a nursing home, to collect a sample for COVID-19 diagnostic testing. Medicare will pay a collection fee and for the travel. The nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is \$23.46 and for individuals in a SNF or whose samples are collected by a laboratory on behalf of an HHA is \$25.46.
- If a patient is already receiving Medicare home health services, the home health nurse, during an otherwise covered visit, could obtain the sample to send to the laboratory for COVID-19 diagnostic testing.
- If a visiting nurse has an otherwise covered RHC or FQHC visit, they can obtain a sample to send to the laboratory for COVID-19 diagnostic testing.

Patients Over Paperwork

- *Accelerated/Advance Payments:* In order to increase cash flow to providers impacted by COVID-19, CMS has expanded our current Accelerated and Advance Payment Program. An accelerated/advance payment is a payment intended to provide necessary funds when there is a disruption in claims submission and/or claims processing. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider/supplier who submits a request to the appropriate Medicare Administrative Contractor (MAC) and meets the required qualifications. Each MAC will work to review requests and issue payments within seven calendar days of receiving the request. Traditionally repayment of these advance/accelerated payments begins at 90 days, however for the purposes of the COVID-19 pandemic, CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment. Providers can get more information on this process here: www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf
- *Provider Enrollment:* CMS has established toll-free hotlines for all providers as well as the following flexibilities for provider enrollment:

- » Waive certain screening requirements.
- » Postpone all revalidation actions.
- » Expedite any pending or new applications from providers.

Medicare appeals in Fee for Service, MA and Part D

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);
- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Cost Reporting

- CMS is delaying the filing deadline of certain cost report due dates due to the COVID-19 outbreak. We are currently authorizing delay for the following fiscal year end (FYE) dates. CMS will delay the filing deadline of FYE 10/31/2019 cost reports due by March 31, 2020 and FYE 11/30/2019 cost reports due by April 30, 2020. The extended cost report due dates for these October and November FYEs will be June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports due by May 31, 2020. The extended cost report due date for FYE 12/31/2019 will be July 31, 2020.

Clinical Laboratory Improvement Act (CLIA) Guidance

- CMS' will exercise enforcement discretion to facilitate pathologists' ability to review pathology slides remotely.
- Expedited CLIA certificate review and application process to ensure that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible during the public health emergency.

- CMS is allowing laboratories within a hospital/University Hospital Campus to hold a single certificate for the laboratory sites within the same physical location or street address to expand testing capacity in these shared locations.
- CMS has clarified that alternate specimen collection devices and media may be used to collect and transport COVID-19 samples.

Additional Guidance

- The Interim Final Rule and waivers can be found at <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency can be found at: <https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>